PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 95 096 a/se	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 02/11082	International filing date *(day/month/year)* 02.10.2002	Priority date *(day/month/year)* 02.10.2001
International Patent Classification (IPC) or both national classification and IPC A61F2/06		
Applicant ANGIOMED GMBH & CO. MEDIZINTECHNIK KG et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the opinion
   II ☐ Priority
   III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   IV ☐ Lack of unity of invention
   V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   VI ☐ Certain documents cited
   VII ☐ Certain defects in the international application
   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28.04.2003	07.01.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Portoni, L Telephone No. +49 89 2399-2345

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 02/11082

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-14 as originally filed

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2, 5, 6, 9-14
	No:	Claims	1, 3, 4, 7, 8
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-14
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents, which have been cited in the International Search Report:

   D1: US-A-5 534 007
   D2: EP-A-0 611 556
   D3: EP-A-1 095 634
   D4: EP-A-0 380 873

2. Document D1 discloses (see in particular from line 62, column 2, to line 38, column 4, and from line 42, column 6, to line 5, column 7; figures 1 and 8; the references in parentheses applying to this document) a stent delivery system comprising a sleeve (40) to surround a self-expanding stent (35), an abutment (60) to engage the stent, a tubular lumen-defining catheter shaft (10) extending proximally from the abutment, a tension member (45) for proximal retraction of the sleeve relative to the stent, the catheter shaft including a proximal guidewire lumen exit port remote from the proximal end of the catheter shaft and the tubular shaft carrying at its distal end an inner catheter which defines a guidewire lumen (15), wherein the inner catheter and the tubular shaft are arranged parallel between the distal end of the catheter shaft and the proximal guidewire exit port with spacing therebetween to accommodate the tension member outside the guidewire lumen and inside the lumen of the catheter shaft, as defined in independent claim 1 of the present international application.

   Therefore, the present international application does not meet the requirements of Article 33(2) PCT, because the subject-matter of independent claim 1 is not novel over the prior art (Rule 64(1)-(3) PCT).

   Moreover, document D2 also discloses a stent delivery system according to claim 1 with the only difference of the absence of the abutment to engage the stent. In fact, the system described in D2 comprises a balloon

catheter to dilate the stent, but the possibility to use the system in combination with self-expanding stents is explicitly mentioned (see column 4, lines 1-3). In this case it would be obvious for the skilled man to introduce an abutment to engage the stent for the same purpose as in the present application, therefore arriving to a device according to claim 1 without the exercise of inventive skill, in order to solve the problem posed.

3. Dependent claims 2-14 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

- the feature of dependent claim 2 is disclosed in a similar device in document D4 (see column 6, lines 26-30);
- the additional features of dependent claims 3, 4, 7 and 8 have already been disclosed in document D1 as well (see column 7, lines 46-53; column 6, lines 58- 62; column 4, lines 56-65);
- the features of dependent claims 5 and 14 are described in document D3 (see column 9, lines 49-55);
- the feature of dependent claim 6 is disclosed in document D2 (see column 3, lines 42-45);
- the additional feature of the sleeve defined in dependent claim 13 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.
- the additional features of dependent claims 9-12 just define slight constructional changes in the device of the preceding claims which comes within the scope of the customary practice followed by persons skilled in the art. Consequently, the subject-matter of claims 9-12 also lacks an inventive step.